

PTA PCT Rec'd 11 AUG 1998

The demand must be filed directly with the competent International Preliminary Examining Authority or, if two or more Authorities are competent, with the one chosen by the applicant. The full name or two-letter code of that Authority may be indicated by the applicant on the line below:

IPEA/ European Patent Office

09/125122

CHAPTER II

PCT

DEMAND

under Article 31 of the Patent Cooperation Treaty:  
The undersigned requests that the international application specified below be the subject of international preliminary examination according to the Patent Cooperation Treaty.

For International Preliminary Examining Authority use only

Identification of IPEA		Date of receipt of DEMAND	
<b>Box No. I IDENTIFICATION OF THE INTERNATIONAL APPLICATION</b>		Applicant's or agent's file reference RM/X88889/PC	
International application No. PCT/IT97/00040	International filing date (day/month/year) 27 February 1997	(Earliest) Priority date (day/month/year) (28th February 1996)	
Title of invention PHARMACEUTICAL COMPOSITIONS COMPRISING NATURAL HUMAN $\alpha$ -INTERFERON			
<b>Box No. II APPLICANT(S)</b>			
Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.) IFI ISTITUTO FARMACOTERAPICO ITALIANO S.p.A. Via Paolo Frisi, 21/23 00197 ROME ITALY		Telephone No.:  Facsimile No.:  Teleprinter No.:	
State (i.e. country) of nationality: ITALY		State (i.e. country) of residence: ITALY	
Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.) TARRO Giulio IFI ISTITUTO FARMACOTERAPICO ITALIANO S.p.A. Via Paolo Frisi 21/23 00197 ROME ITALY			
State (i.e. country) of nationality: ITALY		State (i.e. country) of residence: ITALY	
Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.) BROZZO Renato IFI ISTITUTO FARMACOTERAPICO ITALIANO S.p.A. Via Paolo Frisi 21/23 00197 ROME ITALY			
State (i.e. country) of nationality: ITALY		State (i.e. country) of residence: ITALY	
<input type="checkbox"/> Further applicants are indicated on a continuation sheet.			

Sheet No. 2

International application No.  
PCT/IT97/00040**Box No. III AGENT OR COMMON REPRESENTATIVE; OR ADDRESS FOR CORRESPONDENCE**The following person is ☒ agent ☐ common representativeand ☐ has been appointed earlier and represents the applicant(s) also for international preliminary examination.☒ is hereby appointed and any earlier appointment of (an) agent(s)/common representative is hereby revoked.☐ is hereby appointed, specifically for the procedure before the International Preliminary Examining Authority, in addition to the agent(s)/common representative appointed earlier.Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)*

BAZZICHELLI Alfredo

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Facsimile No.:

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Teleprinter No.:

612287 ROPAT-I

☐ Mark this check-box where no agent or common representative is/has been appointed and the space above is used instead to indicate a special address to which correspondence should be sent.**Box No. IV STATEMENT CONCERNING AMENDMENTS**

The applicant wishes the International Preliminary Examining Authority\*

(i) ☒ to start the international preliminary examination on the basis of the international application as originally filed.(ii) ☐ to take into account the amendments under Article 34 of☐ the description (amendments attached).☐ the claims (amendments attached).☐ the drawings (amendments attached).(iii) ☐ to take into account any amendments of the claims under Article 19 filed with the International Bureau (a copy is attached).(iv) ☐ to disregard any amendments of the claims made under Article 19 and to consider them as reversed.(v) ☐ to postpone the start of the international preliminary examination until the expiration of 20 months from the priority date unless that Authority receives a copy of any amendments made under Article 19 or a notice from the applicant that he does not wish to make such amendments (Rule 69.1(d)). *(This check-box may be marked only where the time limit under Article 19 has not yet expired.)*

- \* Where no check-box is marked, international preliminary examination will start on the basis of the international application as originally filed or, where a copy of amendments to the claims under Article 19 and/or amendments of the international application under Article 34 are received by the International Preliminary Examining Authority before it has begun to draw up a written opinion or the international preliminary examination report, as so amended.

**Box No. V ELECTION OF STATES**☒ The applicant hereby elects all eligible States *(that is, all States which have been designated and which are bound by Chapter II of the PCT)* except.....*(If the applicant does not wish to elect certain eligible States, the name(s) or country code(s) of those States must be indicated above.)*

Sheet No. 3

International application No.

PCT/IT97/00040

## Box No. VI CHECK LIST

The demand is accompanied by the following documents for the purposes of international preliminary examination:

- |  |        |
|--|--------|
| 1. amendments under Article 34                     |        |
| description  | sheets |
| claims   | sheets |
| drawings   | sheets |
| 2. letter accompanying amendments under Article 34 | sheets |
| 3. copy of amendments under Article 19             | sheets |
| 4. copy of statement under Article 19              | sheets |
| 5. other (specify):                                | sheets |

For International Preliminary Examining Authority use only

received

not received

☐☐☐☐☐☐☐☐☐☐☐☐☐☐

The demand is also accompanied by the item(s) marked below:

- |  |  |
|--|--|
| 1. <input type="checkbox"/> separate signed power of attorney      | 4. <input checked="" type="checkbox"/> fee calculation sheet |
| 2. <input type="checkbox"/> copy of general power of attorney      | 5. <input type="checkbox"/> other (specify):                 |
| 3. <input type="checkbox"/> statement explaining lack of signature |  |

## Box No. VII SIGNATURE OF APPLICANT, AGENT OR COMMON REPRESENTATIVE

Next to each signature, indicate the name of the person signing and the capacity in which the person signs (if such capacity is not obvious from reading the demand).



Alfredo Bazzichelli

For International Preliminary Examining Authority use only

1. Date of actual receipt of DEMAND:

2. Adjusted date of receipt of demand due to CORRECTIONS under Rule 60.1(b):

3. ☐ The date of receipt of the demand is AFTER the expiration of 19 months from the priority date and item 4 or 5, below, does not apply.

☐ The applicant has been informed accordingly.

4. ☐ The date of receipt of the demand is WITHIN the period of 19 months from the priority date as extended by virtue of Rule 80.5.

5. ☐ Although the date of receipt of the demand is after the expiration of 19 months from the priority date, the delay in arrival is EXCUSED pursuant to Rule 82.

For International Bureau use only

Demand received from IPEA on:

## PCT

## CHAPTER II

## FEE CALCULATION SHEET

Annex to the Demand for international preliminary examination

<div style="border: 1px solid black; padding: 2px; margin-bottom: 2px;">International application No. <b>PCT/IT97/00040</b></div> <div style="border: 1px solid black; padding: 2px;">Applicant's or agent's file reference <b>RM/X88889/PC</b></div> <div style="border: 1px solid black; padding: 2px; margin-top: 2px;">Applicant <b>IFI ISTITUTO FARMACOTERAPICO ITALIANO S.p.A. et al.</b></div>	<div style="border: 1px solid black; padding: 2px; margin-bottom: 2px;">For International Preliminary Examining Authority use only</div> <div style="border: 1px solid black; padding: 2px; height: 100px; vertical-align: top;">Date stamp of the IPEA</div>																
<div>Calculation of prescribed fees</div> <table style="width: 100%; border-collapse: collapse; margin-top: 10px;"><tr><td style="width: 40%;">1. Preliminary examination fee .....</td><td style="width: 20%; border: 1px solid black; padding: 2px; text-align: center;">DEM 3000</td><td style="width: 10%; border: 1px solid black; text-align: center;">P</td><td style="width: 30%;"></td></tr><tr><td>2. Handling fee .....</td><td style="border: 1px solid black; padding: 2px; text-align: center;">DEM 292</td><td style="border: 1px solid black; text-align: center;">H</td><td></td></tr><tr><td>3. Total of prescribed fees Add the amounts entered at P and H and enter total in the TOTAL box .....</td><td colspan="3" style="border: 1px solid black; padding: 5px; text-align: center;">DEM 3292</td></tr><tr><td></td><td colspan="3" style="border: 1px solid black; padding: 2px; text-align: center;">TOTAL</td></tr></table>		1. Preliminary examination fee .....	DEM 3000	P		2. Handling fee .....	DEM 292	H		3. Total of prescribed fees Add the amounts entered at P and H and enter total in the TOTAL box .....	DEM 3292				TOTAL		
1. Preliminary examination fee .....	DEM 3000	P															
2. Handling fee .....	DEM 292	H															
3. Total of prescribed fees Add the amounts entered at P and H and enter total in the TOTAL box .....	DEM 3292																
	TOTAL																
<div>Mode of Payment</div> <table style="width: 100%; border-collapse: collapse; margin-top: 10px;"><tr><td style="width: 35%;"><input checked="" type="checkbox"/> authorization to charge deposit account with the IPEA (see below)</td><td style="width: 35%;"><input type="checkbox"/> cash</td></tr><tr><td><input type="checkbox"/> cheque</td><td><input type="checkbox"/> revenue stamps</td></tr><tr><td><input type="checkbox"/> postal money order</td><td><input type="checkbox"/> coupons</td></tr><tr><td><input type="checkbox"/> bank draft</td><td><input type="checkbox"/> other (specify):</td></tr></table>		<input checked="" type="checkbox"/> authorization to charge deposit account with the IPEA (see below)	<input type="checkbox"/> cash	<input type="checkbox"/> cheque	<input type="checkbox"/> revenue stamps	<input type="checkbox"/> postal money order	<input type="checkbox"/> coupons	<input type="checkbox"/> bank draft	<input type="checkbox"/> other (specify):								
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<input type="checkbox"/> cheque	<input type="checkbox"/> revenue stamps																
<input type="checkbox"/> postal money order	<input type="checkbox"/> coupons																
<input type="checkbox"/> bank draft	<input type="checkbox"/> other (specify):																
<div>Deposit Account Authorization <i>(this mode of payment may not be available at all IPEAs)</i></div> <p>The IPEA/ <u>EPO</u> <input checked="" type="checkbox"/> is hereby authorized to charge the total fees indicated above to my deposit account.</p> <p><input type="checkbox"/> <i>(this check-box may be marked only if the conditions for deposit accounts of the IPEA so permit)</i> is hereby authorized to charge any deficiency or credit any overpayment in the total fees indicated above to my deposit account.</p> <div style="display: flex; justify-content: space-between; margin-top: 20px;"><div>28070048</div><div>25 September 1997</div><div style="text-align: right;"> Alfredo Bazzichelli</div></div> <div style="display: flex; justify-content: space-between; margin-top: 10px;"><div>Deposit Account Number</div><div>Date (day/month/year)</div><div>Signature</div></div>																	

PATENT COOPERATION TREATY

PCT Rec'd 11 AUG 1998

PCT

09/125122

## INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference <b>PC-23258</b>	<b>FOR FURTHER ACTION</b> see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
International application No. <b>PCT/IT 97/00040</b>	International filing date (day/month/year) <b>27/02/1997</b>	(Earliest) Priority Date (day/month/year) <b>28/02/1996</b>
Applicant <b>IFI ISTITUTO FARMACOTERAPICO ITALIANO...et al.</b>		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 3 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. ☐ Certain claims were found unsearchable (see Box I).

2. ☐ Unity of invention is lacking (see Box II).

3. ☐ The international application contains disclosure of a nucleotide and/or amino acid sequence listing and the international search was carried out on the basis of the sequence listing

☐ filed with the international application.

☐ furnished by the applicant separately from the international application,

☐ but not accompanied by a statement to the effect that it did not include matter going beyond the disclosure in the international application as filed.

☐ Transcribed by this Authority

4. With regard to the title, ☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the abstract,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this International Search Report, submit comments to this Authority.

6. The figure of the drawings to be published with the abstract is:

Figure No. \_\_\_\_\_ ☐ as suggested by the applicant.

☐ because the applicant failed to suggest a figure.

☐ because this figure better characterizes the invention.

☐ None of the figures.

International Application No.

PCT/IT 97/00040

A. CLASSIFICATION OF SUBJECT MATTER  
IPC 6 A61K38/21

According to International Patent Classification (IPC) or to both national classification and IPC:

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 88 03411 A (AMARILLO CELL CULTURE COMPANY) 19 May 1988 see the whole document ---	1-6
X	ARCHIVUM IMMUNOLOGIAE ET THERAPIAE EXPERIMENTALIS 41 (3-4). 1993. 259-265, XP000674716 GEORGIADES J A: "Early changes in the plasma proteins of patients treated with low doses of oral natural human interferon alpha ( IFN -alpha)." see the whole document --- -/--	1-6

☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

\* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubt on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&amp;" document member of the same patent family

Date of the actual completion of the international search

13 June 1997

Date of mailing of the international search report

7. 07. 97

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2  
NL - 2280 HV Rijswijk  
Tel (+ 31-70) 340-2040, Tx. 31 651 epo nl,  
Fax (+ 31-70) 340-3016

Authorized officer

Moreau, J

## INTERNATIONAL SEARCH REPORT

International Application No.

PCT/IT 97/00040

## C (Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	ARCHIVUM IMMUNOLOGIAE ET THERAPIAE EXPERIMENTALIS 41 (3-4). 1993. 237-240, XP000674717 RATAJCZAK B: "Observation of the effect of low oral doses of human leukocytic interferon alpha in children with chronic HBV infection and impaired immune responses." see the whole document	1-6
P,X	ARCHIVUM IMMUNOLOGIAE ET THERAPIAE EXPERIMENTALIS 44 (5-6). 1996. 359-366, XP000674715 ZIELINSKA W ET AL: "Comparison of the long-term effects of treatment with oral and parenteral interferon alpha in chronic viral hepatitis patients." see the whole document -----	1-6

## INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/IT 97/00040

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 8803411 A	19-05-88	AU 625431 B	09-07-92
		AU 1222788 A	01-06-88
		AU 2634592 A	03-12-92
		CA 1320905 A	03-08-93
		DE 3789239 D	07-04-94
		DE 3789239 T	16-06-94
		EP 0341258 A	15-11-89
		HK 24695 A	03-03-95
		IE 61337 B	02-11-94
		KR 9603377 B	09-03-96
		NO 176995 B	27-03-95
		OA 9144 A	31-10-91
		US 5019382 A	28-05-91
		ZA 8708295 A	03-05-88



## PATENT COOPERATION TREATY

From the  
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

09/125122

PCT

To

IFI ISTITUTO FARMACOTERAPICO  
ITALIANO S P A  
Via Paolo Frisi, 21/23  
00197 Roma  
ITALIE

NOTIFICATION OF TRANSMITTAL OF  
THE INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT

(PCT Rule 71.1)

Date of mailing  
(day/month/year)

09.06.98

Applicant's or agent's file reference  
RM/X88889/PC

## IMPORTANT NOTIFICATION

International application No  
PCT/IT97/00040

International filing date (day/month/year)  
27/02/1997

Priority date (day/month/year)  
28/02/1996

Applicant

IFI ISTITUTO FARMACOTERAPICO ITALIANO...et al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

## 4 REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA:



European Patent Office  
D-80298 Munich  
Tel (+49-89) 2399-0. Tx 523656 upmu d  
Fax (+49-89) 2399-4465

Authorized officer

Senkel, H

Tel. (+49-89) 2399-8071



## PATENT COOPERATION TREATY

## PCT

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference RM/X88889/PC	<b>FOR FURTHER ACTION</b>		See Notification of Transmittal of International Preliminary Examination Report (PCT/IPEA/416)
International application No PCT/IT97/00040	International filing date (day/month/year) 27/02/1997	Priority date (day/month/year) 28/02/1996	
International Patent Classification (IPC) or national classification and IPC A61K38/21			
Applicant IFI INSTITUTO FARMACOTERAPICO ITALIANO...et al.			

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36



2. This REPORT consists of a total of 5 sheets, including this cover sheet.

- ☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT)

These annexes consist of a total of sheets

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☒ Certain defects in the international application
- VIII ☒ Certain observations on the international application

Date of submission of the demand 25/09/1997	Date of completion of this report 09.06.98
Name and mailing address of the IPEA/   European Patent Office D-80298 Munich Tel (+49-89) 2399-0, Tx 523656 epmu d Fax (+49-89) 2399-4465	Authorized officer  Villa Riva, A  Telephone No (+49-89) 2399-8404 

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. PCT/IT97/00040

**I. Basis of the report**

1. This report has been drawn on the basis of (*substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.*)

**Description, pages:**

1-12 filed with the demand

**Claims, No.:**

1-6 filed with the demand

2. The amendments have resulted in the cancellation of:

- ☐ the description, pages:  
☐ the claims, Nos.:  
☐ the drawings, sheets:

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

4. Additional observations, if necessary:

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. Statement**

Novelty (N)	Yes:	Claims 1,5,6
	No:	Claims 2-4
Inventive step (IS)	Yes:	Claims
	No:	Claims 1-6
Industrial applicability (IA)	Yes:	Claims 1-6
	No:	Claims

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**International application No PCT/IT97/00040

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**2. Citations and explanations****see separate sheet****VII. Certain defects in the international application**

The following defects in the form or contents of the international application have been noted.

**see separate sheet****VIII. Certain observations on the international application**

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

**see separate sheet**

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT - SEPARATE SHEET**

International application No PCT/IT97/00040

**Section V**

1. Reference is made to the following documents:

D1- WO-A-8 803 411

D2 - Georgiades J.A., Arch.Immunol.Ther.Exp., **41**, 259 (1993).

2. Novelty

The subject-matter of claims 2-4 cannot be considered new in the sense of PCT Art. 33(2). Document D1 discloses the use of human natural  $\alpha$ -interferon in a formulation which can be a solution for peroral administration (see D1, e.g. p. 9, lines 5-11) in a dosage which corresponds to the values of present claim 2 (see D1, p. 5, lines 24-25), for the treatment of neoplastic (D1, p. 9, lines 22-28) and immunologic disease (D1, p. 8, lines 3-5). The fact that  $\alpha$ -interferon is obtained from leukocytes, in particular lymphocytes, or lymphoblastoid cells, like in present claims 3,4 is just standard practice (see e.g. D1, p. 13, lines 21-26 and following, D3, p 239, left column, lines 1-3).

3. Inventive step

The problem to be solved by the present invention may be regarded as to provide an improved administration form of human natural  $\alpha$ -interferon with better patient compliance, high effectiveness and good pharmacokinetics.

D1, which is the closest prior art, as already discussed under point 2., discloses exactly the same solution as in the present application, i.e. the use of human natural  $\alpha$ -interferon in aqueous solution, against immunological, viral and neoplastic diseases. The only difference to present claim 1 is that hepatitis is not mentioned among the viral diseases listed. However, the use of human natural  $\alpha$ -interferon in peroral solid form against hepatitis is known (see e.g. D2, p. 259, left column, lines 1-10 and description p.1, lines 10-15 ).

Therefore, in view of the advantages of the liquid form over the solid one, it would be obvious for the skilled person to combine the teachings of D1 and D2 and adopt the same solution as in present claims 1-2; 6.

As far as the particular drug concentration in claim 6 is concerned, the optimization of the concentration of the active principle in an administration form is a routinary task of the skilled person and does not involve an inventive step. The same is valid for the

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/IT97/00040

subdivision of the composition into dosage units as in claim 5.

**Section VII**

4. Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents D1-D2 is not mentioned in the description, nor are these documents identified therein.

A careful linguistic revision of the description is advisable.

**Section VIII**

5. The expression "appr." in claim 5 is not clear. Abbreviations should be avoided in the wording of the claims. Moreover, only a dosage unit of 1ml, not of "approximately 1 ml" is supported by the description (p.4, line 12). This should be amended to meet the requirements of Art. 6 PCT.
- The expression "UI" (claims 1, 2, and 6, and description) should be changed to "IU", (International Units) as these are the units generally accepted in the art (see also D1).

## PATENT COOPERATION TREATY

PCT

From the INTERNATIONAL BUREAU

NOTIFICATION OF THE RECORDING  
OF A CHANGE(PCT Rule 92bis.1 and  
Administrative Instructions, Section 422)

To:

IFI ISTITUTO FARMACOTERAPICO  
ITALIANO S.P.A.  
Via Paolo Frisi, 21/23  
I-00197 Roma  
ITALIE

<b>Date of mailing (day/month/year)</b> 27 February 1998 (27.02.98)	<b>IMPORTANT NOTIFICATION</b>
<b>Applicant's or agent's file reference</b> RM/X88889/PC	
<b>International application No.</b> PCT/IT97/00040	<b>International filing date (day/month/year)</b> 27 February 1997 (27.02.97)

## 1. The following indications appeared on record concerning:

☐ the applicant
 ☐ the inventor
 ☒ the agent
 ☐ the common representative

<b>Name and Address</b> BAZZICHELLI, Alfredo Società Italiana Brevetti S.p.A. Piazza di Pietra 39 I-00186 Roma Italy	<b>State of Nationality</b>	<b>State of Residence</b>
	<b>Telephone No.</b>	
	<b>Facsimile No.</b>	
	<b>Teleprinter No.</b>	

## 2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:

☒ the person
 ☐ the name
 ☐ the address
 ☐ the nationality
 ☐ the residence

<b>Name and Address</b> IFI ISTITUTO FARMACOTERAPICO ITALIANO S.P.A. Via Paolo Frisi, 21/23 I-00197 Roma Italy	<b>State of Nationality</b>	<b>State of Residence</b>
	<b>Telephone No.</b>	
	<b>Facsimile No.</b>	
	<b>Teleprinter No.</b>	

## 3. Further observations, if necessary:

**The agent has renounced his appointment. All correspondence will now be sent to the applicant indicated in Box 2.**

## 4. A copy of this notification has been sent to:

<input checked="" type="checkbox"/> the receiving Office	<input type="checkbox"/> the designated Offices concerned
<input type="checkbox"/> the International Searching Authority	<input checked="" type="checkbox"/> the elected Offices concerned
<input checked="" type="checkbox"/> the International Preliminary Examining Authority	<input checked="" type="checkbox"/> other: BAZZICHELLI, Alfredo

<b>The International Bureau of WIPO</b> 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No.: (41-22) 740.14.35	<b>Authorized officer</b> F. Gateau Telephone No.: (41-22) 338.83.38
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PATENT COOPERATION TREATY

PCT

From the INTERNATIONAL BUREAU

NOTIFICATION OF THE RECORDING  
OF A CHANGE

(PCT Rule 92bis.1 and  
Administrative Instructions, Section 422)

To:

BAZZICHELLI, Alfredo  
Società Italiana Brevetti S.p.A.  
Piazza di Pietra, 39  
I-00186 Roma  
ITALIE

Date of mailing (day/month/year) 14 October 1997 (14.10.97)	IMPORTANT NOTIFICATION
Applicant's or agent's file reference RM/X88889/PC	
International application No. PCT/IT97/00040	International filing date (day/month/year) 27 February 1997 (27.02.97)

1. The following indications appeared on record concerning:	
<input type="checkbox"/> the applicant	<input type="checkbox"/> the inventor <input checked="" type="checkbox"/> the agent <input type="checkbox"/> the common representative
Name and Address BANCHETTI, Marina Ing. Barzano' & Zanardo Roma S.p.A. Via Piemonte, 26 I-00187 Roma Italy	State of Nationality
	State of Residence
	Telephone No.
	Facsimile No.
2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:	
<input checked="" type="checkbox"/> the person <input type="checkbox"/> the name <input type="checkbox"/> the address <input type="checkbox"/> the nationality <input type="checkbox"/> the residence	
Name and Address BAZZICHELLI, Alfredo Società Italiana Brevetti S.p.A. Piazza di Pietra, 39 I-00186 Roma Italy	State of Nationality
	State of Residence
	Telephone No. 39 6 678 5941
	Facsimile No. 39 6 679 4692
3. Further observations, if necessary:	
4. A copy of this notification has been sent to:	
<input checked="" type="checkbox"/> the receiving Office	<input type="checkbox"/> the designated Offices concerned
<input type="checkbox"/> the International Searching Authority	<input checked="" type="checkbox"/> the elected Offices concerned
<input checked="" type="checkbox"/> the International Preliminary Examining Authority	<input checked="" type="checkbox"/> other: BANCHETTI, Marina

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer F. Gateau
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38



## PATENT COOPERATION TREATY

PCT

## NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

United States Patent and Trademark  
Office  
(Box PCT)  
Crystal Plaza 2  
Washington, DC 20231  
ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

<b>Date of mailing</b> (day/month/year) 14 October 1997 (14.10.97)	
<b>International application No.</b> PCT/IT97/00040	<b>Applicant's or agent's file reference</b> RM/X88889/PC
<b>International filing date</b> (day/month/year) 27 February 1997 (27.02.97)	<b>Priority date</b> (day/month/year) 28 February 1996 (28.02.96)
<b>Applicant</b> TARRO, Giulio et al	

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:25 September 1997 (25.09.97)☐ in a notice effecting later election filed with the International Bureau on:2. The election ☒ was☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

<b>The International Bureau of WIPO</b> 34, chemin des Colombettes 1211 Geneva 20, Switzerland	<b>Authorized officer</b>  F. Gateau
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38

## PATENT COOPERATION TREATY

PCT

## NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

United States Patent and Trademark  
Office  
(Box PCT)  
Crystal Plaza 2  
Washington, DC 20231  
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in its capacity as elected Office

<b>Date of mailing</b> (day/month/year) 14 October 1997 (14.10.97)	
<b>International application No.</b> PCT/IT97/00040	<b>Applicant's or agent's file reference</b> RM/X88889/PC
<b>International filing date</b> (day/month/year) 27 February 1997 (27.02.97)	<b>Priority date</b> (day/month/year) 28 February 1996 (28.02.96)
<b>Applicant</b> TARRO, Giulio et al	

1. The designated Office is hereby notified of its election made:



in the demand filed with the International Preliminary Examining Authority on:

25 September 1997 (25.09.97)



in a notice effecting later election filed with the International Bureau on:

2. The election



was



was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO  
34, chemin des Colombettes  
1211 Geneva 20, Switzerland

Facsimile No.: (41-22) 740.14.35

Authorized officer

F. Gateau

Telephone No.: (41-22) 338.83.38

09/125122

**CORRECTED** PATENT COOPERATION TREATY  
**VERSION**

From the INTERNATIONAL BUREAU

To:

IFI ISTITUTO FARMACOTERAPICO  
ITALIANO S.P.A.  
Via Paolo Frisi, 21/23  
I-00197 Roma  
ITALIE

**NOTIFICATION CONCERNING  
SUBMISSION OR TRANSMITTAL  
OF PRIORITY DOCUMENT**

(PCT Administrative Instructions, Section 411)

Date of mailing (day/month/year) 28 September 1998 (28.09.98)	<b>IMPORTANT NOTIFICATION</b>
Applicant's or agent's file reference RM/X88889/PC	
International application No. PCT/IT97/00040	International filing date (day/month/year) 27 February 1997 (27.02.97)
International publication date (day/month/year) 04 September 1997 (04.09.97)	Priority date (day/month/year) 28 February 1996 (28.02.96)
Applicant IFI ISTITUTO FARMACOTERAPICO ITALIANO S.P.A. et al	

- The applicant is hereby notified of the date of receipt (except where the letters "NR" appear in the right-hand column) by the International Bureau of the priority document(s) relating to the earlier application(s) indicated below. Unless otherwise indicated by an asterisk appearing next to a date of receipt, or by the letters "NR", in the right-hand column, the priority document concerned was submitted or transmitted to the International Bureau in compliance with Rule 17.1(a) or (b).
- This updates and replaces any previously issued notification concerning submission or transmittal of priority documents.
- An **asterisk(\*)** appearing next to a date of receipt, in the right-hand column, denotes a priority document submitted or transmitted to the International Bureau but not in compliance with Rule 17.1(a) or (b). In such a case, **the attention of the applicant is directed** to Rule 17.1(c) which provides that no designated Office may disregard the priority claim concerned before giving the applicant an opportunity, upon entry into the national phase, to furnish the priority document within a time limit which is reasonable under the circumstances.
- The **letters "NR"** appearing in the right-hand column denote a priority document which was not received by the International Bureau or which the applicant did not request the receiving Office to prepare and transmit to the International Bureau, as provided by Rule 17.1(a) or (b), respectively. In such a case, **the attention of the applicant is directed** to Rule 17.1(c) which provides that no designated Office may disregard the priority claim concerned before giving the applicant an opportunity, upon entry into the national phase, to furnish the priority document within a time limit which is reasonable under the circumstances.

<u>Priority date</u>	<u>Priority application No.</u>	<u>Country or regional Office or PCT receiving Office</u>	<u>Date of receipt of priority document</u>
28 Febr 1996 (28.02.96)	RM96A000136	IT	17 Marc 1997 (17.03.97)
14 June 1996 (14.06.96)	RM96A000427	IT	17 Marc 1997 (17.03.97)

The International Bureau of WIPO  
34, chemin des Colombettes  
1211 Geneva 20, Switzerland

Authorized officer

F. Gateau

Facsimile No. (41-22) 740.14.35

Telephone No. (41-22) 338.83.38

## PATENT COOPERATION TREATY

79/125122  
**PCT**

**COMMUNICATION IN CASES FOR WHICH  
NO OTHER FORM IS APPLICABLE**

From the INTERNATIONAL BUREAU

To:

IFI ISTITUTO FARMACOTERAPICO  
ITALIANO S.P.A.  
Via Paolo Frisi, 21/23  
I-00197 Roma  
ITALIE

Date of mailing (day/month/year) 28 September 1998 (28.09.1998)	
Applicant's or agent's file reference RM/X88889/PC	<b>REPLY DUE</b> see paragraph 1 below
International application No. PCT/IT97/00040	International filing date (day/month/year) 27 February 1997 (27.02.1997)
Applicant IFI ISTITUTO FARMACOTERAPICO ITALIANO S.P.A.	

<p>1. <input type="checkbox"/> REPLY DUE within _____ months/days from the above date of mailing</p> <p><input type="checkbox"/> NO REPLY DUE, however, see below -----</p> <p><input checked="" type="checkbox"/> IMPORTANT COMMUNICATION</p> <p><input type="checkbox"/> INFORMATION ONLY</p> <p>2. COMMUNICATION:</p> <p>We acknowledge receipt of your communication dated 22 September 1998, bringing to the attention of the International Bureau that in respect of the above mentioned application, the international publication No. WO 97/31649 mailed on 04 September 1997 (04.09.97) indicated incorrectly the second priority number as RM96A000247 instead of RM96A000427.</p> <p>The International Bureau shall publish a correction in the Section II of the PCT Gazette. A corrected version of the front page of the corresponding PCT pamphlet will also be published.</p> <p>A copy of this notification has been sent to the designated Offices concerned.</p>	
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The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. (41-22) 740.14.35	Authorized officer F. Gateau Telephone No. (41-22) 338.83.38
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